

Material Code M0260

Revision 00

Type PC
 Brand name MAKROLON RX1805
 Supplier COVESTRO/BAYER

Sterilization Stability:

	<u>Compliant</u>	<u>Comments</u>
Gamma Sterilization	YES	Up to 60kGy
Ethylene Oxide	YES	-

Biocompatibility Data:

	<u>Compliant</u>	<u>Standard</u>	<u>Comments</u>
USP Class VI	YES	USP	-
Cytotoxicity	YES	ISO 10993-5	-
Sensitization	YES	ISO 10993-10	-
Irritation or intracutaneous reactivity	YES	ISO 10993-10	-
Systemic toxicity (acute)	YES	ISO 10993-11	-
Hæmocompatibility	YES	ISO 10993-4	-

Main Regulatory Compliances:

	<u>Compliant</u>	<u>Comments</u>
BPA	NO	< 100 ppm
CONEG (Cadmium, chromium, lead and mercury)	YES	Not used in the manufacturing process
Conflict Minerals	YES	Not used in the manufacturing process
European Directive 2002/95/EC & 2011/65/UE - RoHS/RoHS2	YES	Not used in the manufacturing process
Latex or Natural Rubber	YES	Not used in the manufacturing process
Phthalates	YES	Not used in the manufacturing process
TSE / BSE	YES	Not used in the manufacturing process
European Directive (EC 1907/2006) REACH	YES	-
SVHC List	YES	Not used in the manufacturing process
MSDS	YES	-

Technical Characteristics:

	<u>Value</u>	<u>Measuring Method</u>	<u>Comments</u>
Injection	YES	-	-
Density	1200 kg/m3	ISO 1183-1	-
Melt Flow Rate	6.5 g/10 min	ISO 1133	MFR : 300°C/1.2kg
Modulus of Elasticity / Young modulus	2400 MPa	ISO 527-1,-2	-
Tensile Strength at Break	75 Mpa	ISO 527-1,-2	-
Other mechanical property 1	67 MPa	ISO 527-1,-2	Yield stress
Other mechanical property 2	6.3 %	ISO 527-1,-2	Yield strain

R&D Validation	GVA	QA/RA Validation	ABA
Date	08/07/2017	Date	08/07/2017

Please be aware regarding Medical Applications, Technical Characteristics and Regulatory requirements:

Promepla Group does not test or analyze this material for any specified regulatory requirements nor for the any technical data. The information provided by the raw material manufacturers has been compiled by Promepla Group, in a readily retrievable format, as part of our service to you, our customer. Customers and End-Users must themselves determine suitability of use and conduct The Sterilisation Data presented herein, is provided solely for informative purposes only. The Sterilisation stability must be validated by the Customer and/or the End-User. We remain at your disposal should you need any additional information.